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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,181	07/22/1999	GERARD GRASSY	1028-1	2476

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CLOW, LORI A

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1631

26

DATE MAILED: 11/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/359,181	GRASSY ET AL.
	Examiner Lori A. Clow, Ph.D.	Art Unit 1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 26 August 2002.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,4,5,8-10,18-20 and 73 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1,4,5,8-10,18-20 and 73 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .	6) <input type="checkbox"/> Other: _____ .

### **DETAILED ACTION**

Applicants' arguments, filed 26 August 2002, have been fully considered but are not deemed fully persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1, 4, 5, 8-10, 18-20, and 73 are currently pending.

#### ***Claim Rejections-35 USC 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 5, 8-10, and 18-20 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims do not disclose how to practice the invention. Simply "building", "selecting", and "modeling", without any concrete active steps such that one of skill in the art could practice the invention without undue experimentation, does not constitute enabling the said invention.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of

experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

- a) In order to practice the claimed invention one of skill in the art must be able to provide, identify, and describe molecules that exhibit a desired activity by modeling, building, selecting, and filtering.
- b) The specification provides examples for a computer-aided method of describing a molecule.
- c) The specification provides working examples of a set of 19 peptides used as a learning set to define a strategy for rational design.
- d) The invention is drawn to a method for identifying and describing a molecule with a desired activity.
- e) It would have been well known in the art that molecular modeling can be computerized such that molecular descriptors are used to define the molecule of interest. Furthermore, the descriptors can be used to compare to libraries of known and unknown molecules for several iterations in order to identify candidate molecules. The filtering of molecules is also known in that it provides a means of narrowing computational burden and identifying specific candidates. The instant application, however, fails to provide concrete active steps such that one of ordinary skill in the art could practice the invention. Specifically, method steps that adequately describe the process of computationally determining molecular descriptors are not disclosed. What

methods of computation are used? Furthermore, the process for building a combinatorial library using the molecular descriptors is not defined in such a way as to practice that step.

- f) The skill of those in the art of molecular modeling is high.
- g) The prior art indicates molecular design methods using descriptors.
- h) The claims are broad because the claims are not limited to any particular steps, in any particular order that specifically teach how to practice the said invention.

Applicant argues that the generalized concept of “building”, “selecting”, and “modeling” steps are discussed in sufficient detail in the specification to enable a person skilled in the art to practice the claimed invention. This is not persuasive for the reasons stated above. The physiochemical and topological descriptors of said claims are generated by a program called TSAR (page 30)(Oxford Molecular Group). However, nowhere in the specification is one appraised of the framework of this particular software such that one of skill in the art could ascertain specific calculations that allow one to identify descriptors for specific peptides nor are references to this software provided. In particular, the recitation of TSAR as the software used is unclear because as written, TSAR could refer to any of various versions of this software that are available. Therefore, it is unclear exactly what parameters are chosen in order to generate the descriptors. For instance, does the user set parameters or are the parameters built into the program by default, such that descriptors are generated. Furthermore, without disclosure of the steps provided by said software, or alternative steps to build, select, or model, one of skill in the art would not know how to practice the invention.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

***Inquiries***

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242, or (703) 308-4028.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (703) 306-5439. The examiner can normally be reached on Monday-Friday from 10am to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Bill Phillips, whose telephone number is (703) 305-3419, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

November 15, 2002

Lori A. Clow, Ph.D.  
Art Unit 1631  
*Lori A. Clow*

*MARY K. ZEMAN*  
MARY K. ZEMAN  
PRINCIPAL EXAMINER

*1631*